Section 5 510(k) Summary

OCT 1 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment	Siemens Medical Solutions USA. Inc. 51 Valley Stream Parkway Mail Code G01 Malvern, PA 19355, USA
Registration Number	2240869
Manufacturer	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany
Registration Number	8010024
Contact Person	Ms. Kim Rendon Manager, Regulatory Affairs/Clinical Affairs Siemens Healthcare Siemens Medical Solutions USA, Inc. Customer Solutions Group 51 Valley Stream Parkway Mail Code G01 Malvern, PA 19355, USA Phone: (610) 448-1773 Fax: (610) 448-1787

Device Name	Trade Names:	MAGNETOM Aera MAGNETOM Skyra
	Classification Name:	Magnetic Resonance Diagnostic Device
	CFR Code:	21 CFR § 892.1000
	Classification:	Class II

Performance Standards
None established under Section 514 the Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use
The MAGNETOM Aera and the MAGNETOM Skyra systems are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectro-scopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM Aera and the MAGNETOM Skyra systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

Device Description
MAGNETOM Aera (1.5 T) and MAGNETOM Skyra (3 T) are similar to the previously cleared MAGNETOM Espree and MAGNETOM Verio, utilizing a superconducting magnet design. The open bore, whole body scanners are designed for increased patient comfort. They focus on ergonomics and usability to reduce complexity of the MR workflow.

The MAGNETOM Aera and the MAGNETOM Skyra systems will be available in fixed and mobile configurations.

Substantial Equivalence
Siemens feels that the new systems are substantially equivalent to the following predicate devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM Espree (1.5T)	K041112	July 21, 2004
Siemens MAGNETOM Verio (3T)	K072237	October 10, 2007
syngo® MR B17 Software update	K082427	November 7, 2008

General Safety and Effectiveness Concerns:
Operation of the MAGNETOM Aera (1.5T) and the MAGNETOM Skyra (3T) systems is substantially equivalent to the commercially available MAGNETOM Espree (1.5T) and MAGNETOM Verio (3T) System.

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As specified in the FDA guidance document "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Devices" (released Nov. 1998) the following measurements of performance and safety data have been performed following NEMA or equivalent IEC and ISO standards:

Safety:
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels

Performance:
- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile. Thickness and Gap
- High Contrast Spatial Resolution

The MAGNETOM Aera and MAGNETOM Skyra will conform to the measurements of safety parameters to the international IEC, ISO and NEMA standards for safety issues with Magnetic Resonance Imaging Diagnostic Devices.

Furthermore performance measurements have been done on the predicate devices MAGNETOM Espree and MAGNETOM Verio to show that the performance of the MAGNETOM Aera and MAGNETOM Skyra is equivalent with respect to the predicate devices.

This will assure that the performance of these devices can be considered safe and effective with respect to the currently available MAGNETOM Espree and MAGNETOM Verio systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Kim Rendon
Manager, Regulatory/Clinical Affaris
Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy, Mail Code G01
MALVERN PA 19355

OCT 1 2010

Re: K101347
Trade/Device Name: Magnetom Aera and Magnetom Skyra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and LNI
Dated: August 13, 2010
Received: August 16, 2010

Dear Ms. Rendon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101347

Section 4 Indications for Use Statement

510(k) Number (if known) _____

Device Names: **MAGNETOM Aera and MAGNETOM Skyra**

Indications for Use:

The MAGNETOM systems described above are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM systems described above may also be used for imaging during interventional procedures when performed with MR compatible devices such as inroom display and MR-safe biopsy needles.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use____

Michael D. O'Hara for David Brown

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101347